

Atty Dkt 213202.00483



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
DONALD R. RICCI) : Examiner: NYA
Application No.: 10/671,716) : Group Art Unit: 3739
Filed: September 29, 2003) :
For: STENT DELIVERY SYSTEM) : March 23, 2006
AND METHOD OF USE) :

Mail Stop
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATUS REQUEST

Sir:

Applicant would like to know the status of the
above-identified application.

FACTS

The above-identified application was filed as a
continuation application of Appln. No. 09/501,981 in the U.S.
Patent and Trademark Office on September 29, 2003 (see date
stamped postcard and Utility Patent Application Transmittal
attached). The application was filed with a specification
comprising seventeen (17) pages, six (6) sheets of informal
drawings, a copy of the Declaration from parent Appln. No.
09/501,981, an Information Disclosure Statement, a

BEST AVAILABLE COPY

Preliminary Amendment, and a Petition Under 37 CFR 1.136 for a five month extension of time for parent Appln. No.

09/501,981. A copy of the above documents are attached.

Since the September 29, 2003 filing date, Applicant has received the following:

The postcard with the application number affixed thereto (receipt date unknown);

The Official Filing Receipt (received Dec. 29, 2003);

Notice of New Or Revised Projected Publication Date (received March 29, 2004); and

Notice of Publication Of Application (received June 2, 2004).

Applicant has received nothing to date since June 2, 2004. Therefore, Applicant respectfully requests the status of the above-identified application.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3507.

All correspondence should continue to be directed to our
address given below.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Richard P. Bauer", is written over a horizontal line.

Attorney for Applicant
Richard P. Bauer
Registration No. 31,588

PATENT ADMINISTRATOR
KATTEN MUCHIN ZAVIS ROSENMAN
525 West Monroe Street
Chicago, Illinois 60661-3693
Facsimile: (312) 902-1061



DOCKETED

Mail Stop Patent appn.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Date 9/29/03
Atty. Docket No. 213202
00483

Sir:

- Kindly acknowledge receipt of the accompanying:
- ☒ Specifications, claims and abstract 17 pages, with Transmittal Form.
 - ☒ Oath or Declaration and Power of Attorney ☒ Executed ☐ Not Executed Copy
 - ☒ 6 Sheets of Formal ☒ Informal Drawings
 - ☒ Check for \$ 455.00 (filing fee) Dep. work.
 - ☒ Small Entity Declaration
 - ☒ Assignment, PTO-1595 and Check for \$
 - ☒ Transmittal Under 37 C.F.R. § 1.136 and Check for \$ 985 (Dep. work)
 - ☒ Other (specify) Prelim Amend & IDS w/ 1448 Pet Under

by placing your receiving date stamp hereon and returning to deliverer.

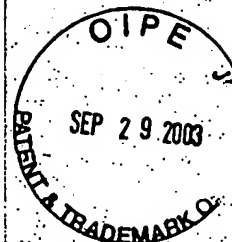
Atty./Sec.:

RPBldem

Due Date

9 29 03

37 C.F.R.
1.136(a)
for 5 mo.
EDT





UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.

213202.00483

First Named Inventor or Application Identifier

DONALD R. RICCI

Express Mail Label No.

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO:

Commissioner for Patents
Box Patent Application
Washington, DC 20231

1. ☒ Fee Transmittal Form
(Submit an original, and a duplicate for fee processing)

2. ☒ Applicant claims small entity status.
See 37 CFR 1.27.

3. ☒ Specification Total Pages

4. ☒ Drawing(s) (35 USC 113) Total Sheets

5. ☒ Oath or Declaration Total Pages

a. ☐ Newly executed (original or copy)

b. ☒ Copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional with Box 17 completed)

i. ☐ **DELETION OF INVENTOR(S)**
Signed Statement attached deleting
inventor(s) named in the prior application, see
37 CFR 1.63(d)(2) and 1.33(b).

6. ☒ Application Data Sheet. See 37 CFR 1.76

7. ☐ CD-ROM or CD-R in duplicate, large table or Computer
Program (Appendix)

8. ☐ Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)

a. ☐ Computer Readable Form (CRF)

b. Specification Sequence Listing on:

i. ☐ CD-ROM or CD-R (2 copies); or

ii. ☐ paper

c. ☐ Statements verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. ☐ Assignment Papers (cover sheet & document(s))

10. ☐ 37 CFR 3.73(b) Statement ☐ Power of Attorney
(when there is an assignee)

11. ☐ English Translation Document (if applicable)

12. ☒ Information Disclosure ☐ Copies of IDS
Statement (IDS)/PTO-1449 Citations

13. ☒ Preliminary Amendment

14. ☒ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)

15. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)

16. ☒ Other: Small Entity Statement; Petition Under 37 CFR
1.136(a) for 09/501,981 for five (5) months

17. If a CONTINUING APPLICATION, check appropriate box and supply the requisite information:

☒ Continuation

☐ Divisional

☐ Continuation-in-part (CIP) of prior application No. 09/501,981

Prior application information:

Examiner: L. THAHN

Group/Art Unit: 3763

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

18. CORRESPONDENCE ADDRESS

☒ Customer Number or Bar Code Label

27160
(Insert Customer No. or Attach bar code label here)

or ☐ Correspondence address below

NAME

Address

City

State

Zip Code

Country

Telephone

Fax



CLAIMS	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
	TOTAL CLAIMS (37 CFR 1.16(c))	24 -20 =	1	X \$ 18.00 =	\$ 72.00
	INDEPENDENT CLAIMS (37 CFR 1.16(b))	4 -3 =	1	X \$ 84.00 =	\$ 84.00
	MULTIPLE DEPENDENT CLAIMS (if applicable) (37 CFR 1.16(d))			\$280.00 =	\$000.00
				BASIC FEE (37 CFR 1.16(a))	\$750.00
			Total of above Calculations =		\$906.00
	Reduction by 50% for filing by small entity (Note 37 CFR 1.9, 1.27, 1.28).				\$453.00
	TOTAL =				\$453.00

19. Small entity status

- a. ☐ A small entity statement is enclosed
- b. ☐ A small entity statement was filed in the prior nonprovisional application and such status is still proper and desired.
- c. ☐ Is no longer claimed.

20. ☐ A check in the amount of \$ _____ to cover the filing fee is enclosed.

21. ☐ A check in the amount of \$ _____ to cover the recordal fee is enclosed.

22. The Commissioner is hereby authorized to charge the above fees or credit overpayments or charge any deficiencies to Deposit Account No. 50-1710:

- a. ☒ Fees required under 37 CFR 1.16.
- b. ☒ Fees required under 37 CFR 1.17.
- c. ☐ Fees required under 37 CFR 1.18.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED	
NAME	RICHARD P. BAUER, REG. NO. 31,588
SIGNATURE	
DATE	September 29, 2003



INVENTOR INFORMATION

Inventor One Given Name:: DONALD R.
Family Name:: RICCI
Postal Address Line One:: 4443 West 3rd Avenue
City:: Vancouver
State or Province:: British Columbia
Country:: Canada
Postal or Zip Code:: V6R 1M9
City of Residence:: Vancouver
State or Province of Residence:: British Columbia
Country of Residence:: Canada
Citizenship Country:: Canada

CORRESPONDENCE INFORMATION

Correspondence Customer Number:: 27160
Fax:: (312) 902-1061

APPLICATION INFORMATION

Title Line One:: STENT DELIVERY SYSTEM AND METHOD OF USE
Total Drawing Sheets:: Six (6)
Informal Drawings?: Yes
Application Type:: Utility
Docket Number:: 213202.00483
Secrecy Order in Parent Appl.?: No

REPRESENTATIVE INFORMATION

Representative Customer Number:: 27160

PRIOR FOREIGN OR US APPLICATIONS

U.S. Application One:: 09/501,981
Filing Date:: February 11, 2000
Country:: USA
Priority Claimed:: Yes



Gowlings Ref: T8465396US
Novo RPS Ref: Challoon

FINAL VERSION

Applicant/Inventor: Donald R. Ricci

Title: Stent Delivery System and Method of Use

Jurisdiction: United States

Date: February 11, 2000

INTELLECTUAL PROP. 217676_2



BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

In one of its aspects, the present invention relates to a balloon dilation catheter. In another of its aspects, the present invention relates to a catheterization method.

5

BRIEF DESCRIPTION OF THE PRIOR ART

Balloon dilation catheters have been known for many years. Originally, such catheters were used in interventional techniques such as angioplasty.

10 In recent years, balloon dilation catheters have also been used to facilitate endovascular prosthesis' such as stents. Stents are generally known. Indeed, the term "stent" has been used interchangeably with terms such as "intraluminal vascular graft" and "expandable prosthesis". As used throughout this specification, the term "stent" is intended to have a broad meaning and encompasses any expandable prosthetic device for implantation in a body passageway (e.g., a lumen or artery).

15 In the past dozen years, the use of stents has attracted an increasing amount of attention due to the potential of these devices to be used, in certain cases, as an alternative to surgery. Generally, a stent is used to obtain and maintain the patency of the body passageway while maintaining the integrity of the passageway. As used in this specification, the term "body passageway" is intended to have a broad meaning and encompasses any duct
20 (e.g., natural or iatrogenic) within the human body and can include a member selected from the group comprising: blood vessels, respiratory ducts, gastrointestinal ducts and the like.

Stent development has evolved to the point where the vast majority of currently available stents rely on controlled plastic deformation of the entire structure of the stent at the target body passageway so that only sufficient force to maintain the patency of the body
25 passageway is applied during expansion of the stent.

Generally, in many of these systems, a stent, in association with a balloon, is delivered to the target area of the body passageway by a catheter system. Once the stent has been properly located (for example, for intravascular implantation the target area of the vessel can be filled with a contrast medium to facilitate visualization during fluoroscopy), the balloon is

expanded thereby plastically deforming the entire structure of the stent so that the latter is urged in place against the body passageway. As indicated above, the amount of force applied is at least that necessary to expand the stent (i.e., the applied force exceeds the minimum force above which the stent material will undergo plastic deformation) while maintaining the
5 patency of the body passageway. At this point, the balloon is deflated and withdrawn within the catheter, and is subsequently removed. Ideally, the stent will remain in place and maintain the target area of the body passageway substantially free of blockage (or narrowing).

See, for example, any of the following patents:

- 10 United States patent 4,323,071 (Simpson et al.),
United States patent 4,411,055 (Simpson et al.),
United States patent 4,616,648 (Simpson),
United States patent 4,661,094 (Simpson),
United States patent 4,733,665 (Palmaz),
- 15 United States patent 4,739,762 (Palmaz),
United States patent 4,800,882 (Gianturco),
United States patent 4,907,336 (Gianturco),
United States patent 5,035,706 (Gianturco et al.),
United States patent 5,037,392 (Hillstead),
- 20 United States patent 5,041,126 (Gianturco),
United States patent 5,092,873 (Simpson et al.),
United States patent 5,102,417 (Palmaz),
United States patent 5,147,385 (Beck et al.),
United States patent 5,269,793 (Simpson),
- 25 United States patent 5,282,824 (Gianturco),
United States patent 5,316,023 (Palmaz et al.),
United States patent 5,415,634 (Glynn et al.),
United States patent 5,462,529 (Simpson et al.),
United States patent 5,755,771 (Penn et al.),

United States patent 5,980,570 (Simpson),
International patent application PCT/CA97/00151 (Penn et al.), and
International patent application PCT/CA97/00152 (Penn et al.),

5 for a discussion on previous stent designs and deployment systems.

Given the development of stent design, the prior art has also focussed on delivery systems for stent deployment.

One particular delivery system is taught by United States patent 4,748,982 [Horzewski et al. (Horzewski)]. Horzewski teaches a reinforced balloon dilation catheter
10 with a slitted exchange sleeve. Essentially, the catheter comprises a tubular member having a first lumen and a second lumen. A dilation balloon is mounted on the distal end of the tubular member and is in communication with the first lumen. An opening (or notch) is disposed in the tubular member intermediate its proximal and distal ends for receiving a guidewire which travels through the second lumen and emanates out of the distal end of the
15 tubular member. A slit is disposed on the longitudinal portion of the tubular member between the opening and an area 0.5-1 cm proximal the dilation balloon. Thus, as illustrated in Figure 1 of Horzewski, the guidewire travels partly within a lumen in the catheter (approximately 10-15 cm) and partly along the outside of the catheter (approximately 80-90 cm). This approach is also known as a "monorail" delivery system. The principal advantage of this approach is
20 that it permits so-called "rapid exchange" of the balloon catheter with another balloon catheter. In design, the exchange is facilitated by the provision of the above-mentioned slit so that the actual exchange is done over the balloon portion only (approximately 3 cm). The principal disadvantages of this approach include: less than optimum steerability of the guidewire, difficulties in moving the guidewire with respect to the catheter, less than optimum
25 torque control and inability to exchange the guidewire while leaving the catheter in place. The catheter illustrated by Horzewski has not gained widespread commercial popularity.

Another approach for catheterization is the so-called "over the wire" approach - this approach is discussed in many of the above-mentioned United States patents naming John P. Simpson as an inventor. In this approach, the catheter comprises a tubular member having

a first lumen and a second lumen. A dilation balloon is mounted on the distal end of the tubular member and is in communication with the first lumen. The second lumen runs through the length of the tubular member. An opening is disposed in the tubular member at its proximal end for receiving a guidewire which travels through second lumen and emanates out of the distal end of the tubular member. Thus, in the "over the wire" approach, the guidewire is enpassed by the second lumen along the entire length of the tubular member (approximately 90-105 cm). The principal advantages of the this approach include: optimum steerability, smoother movement of the guidewire with respect to the catheter (due to the coaxial relationship thereof), optimum torque control and the ability to exchange the guidewire while leaving the catheter in place. The principal disadvantage of this approach is that exchange with another balloon catheter is relatively cumbersome (i.e., compared to the "monorail" approach discussed above.

Accordingly, it would be desirable to have a balloon dilation catheter which combined the advantages of the above-mentioned "monorail" approach and "over the wire" approach while obviating or mitigating the disadvantages of these approaches. It would be further advantageous if the balloon dilation catheter were readily adaptable to be used in various interventional techniques such as endovascular prosthesis delivery, angioplasty and the like.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a novel balloon dilation catheter.

It is another object of the present invention to provide a novel catheterization method.

Accordingly, in one of its aspects, the present invention provides a balloon dilation catheter comprising:

- a tubular member having a proximal end and a distal end;
- an inflatable balloon disposed at the distal end of the tubular member;
- a first lumen disposed in the tubular member and in communication with an interior of the inflatable balloon;

a second lumen disposed in the tubular member for receiving a guidewire substantially along its entire length, the second lumen having a first opening at the proximal end of the tubular member and a second opening at the distal end of the tubular member; and

5 a first slit disposed longitudinally from the first opening along substantially the entire length of the tubular member to permit separation of the guidewire with respect to the second lumen.

In another of its aspects, the present invention provides a catheterization kit comprising:

10 a guide catheter;
a guide wire; and

a balloon dilation catheter comprising: a tubular member having a proximal end and a distal end; an inflatable balloon disposed at the distal end of the tubular member;

15 a first lumen disposed in the tubular member and in communication with an interior of the inflatable balloon; a second lumen disposed in the tubular member for receiving the guidewire substantially along its entire length, the second lumen having a first opening at the proximal end of the tubular member and a second opening at the distal end of the tubular member; and a first slit disposed longitudinally from the first opening along substantially the entire length of the tubular member to permit separation of the guidewire with respect to the second lumen.

20 In yet another of its aspects, the present invention provides a stent-mounted balloon catheter comprising:

a tubular member having a proximal end and a distal end;
an inflatable balloon disposed at the distal end of the tubular member;
a stent mounted on the inflatable balloon;
25 a first lumen disposed in the tubular member and in communication with an interior of the inflatable balloon;

a second lumen disposed in the tubular member for receiving a guidewire substantially along its entire length, the second lumen having a first opening at the proximal end of the tubular member and a second opening at the distal end of the tubular member; and

a first slit disposed longitudinally from the first opening along substantially the entire length of the tubular member to permit separation of the guidewire with respect to the second lumen.

Thus, the present inventors have discovered a balloon catheter which combines the advantages of the "over the wire" approach (i.e., optimum steerability, smoother movement of the guidewire with respect to the catheter (due to the coaxial relationship thereof), optimum torque control and the ability to exchange the guidewire while leaving the catheter in place) with the principal advantage of the "monorail" approach (i.e., rapid exchange of the balloon catheter with another balloon catheter while leaving the guidewire in place).

As used throughout this specification, the term "tubular member", when used in the context of the present balloon dilation catheter is intended to mean a portion of the catheter generally tubular in construction and generally representing the large majority of the overall length of the balloon dilation catheter. Typically, the tubular member will be at least about 75%, more preferably at least about 85%, most preferably at least about 95%, of the overall length of the balloon dilation catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the present invention will be described with reference to the accompanying drawings wherein like numerals designate like parts and in which:

Figure 1 illustrates a perspective view of an embodiment of the present balloon dilation catheter;

Figure 2 is a sectional view along line II-II in Figure 1;

Figure 3 is a sectional view along line III-III in Figure 1;

Figure 4 illustrates an exploded view of modified proximal end of the balloon dilation catheter illustrated in Figure 1;

Figures 5-11 illustrate steps in various catheterization techniques employing the present balloon dilation catheter;

Figure 12 illustrates a modified balloon for use in the present balloon dilation catheter; and

Figure 13 illustrates a preferred embodiment of a modified tubular member for use in the present balloon dilation catheter.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

5 Thus, with reference to Figures 1-3, there is illustrated a balloon dilation catheter 100. Balloon dilation catheter 100 comprises a proximal end 105 and a distal end 110. Distal end 110 of balloon dilation catheter 100 comprises an expandable balloon 115. Proximal end 105 of balloon dilation catheter 100 comprises a single lumen Luer-type adaptor 120. Disposed between adaptor 120 and balloon 115 is a tubular member 125.

10 As will be apparent from Figure 1, disposed in tubular member 125 is an opening 130. Also disposed in tubular member 125 is a slit 135 which extends from opening 130 to a point in tubular member 125 just proximal balloon 115.

 With particular reference to Figures 2 and 3, tubular member 125 comprises a first lumen 140 and a second lumen 150. First lumen 140 is designed to be in communication with
15 an interior of balloon 115. The design of the interface between balloon 115 and first lumen 140 is conventional - see for example Horzewski referred to hereinabove. The construction of tubular member 125 having opening 130, slit 135, first lumen 140 and second lumen 150 is conventional - see Horzewski referred to hereinabove.

 With further reference to Figures 1-3, it will be apparent that opening 130 is designed
20 to receive a guidewire 160. Guidewire 160 passes through second lumen 150 and out of a distal opening of tubular member 125 beyond balloon 115.

 In Figure 4, there is illustrated a modification of balloon dilation catheter 100 illustrated in Figures 1-3.

 Specifically, in Figure 4, Luer-type adaptor 120a is modified to contain a lumen 150a
25 in communication with a slit 135a. As will be apparent to those of skill in the art, lumen 150a is in communication with second lumen 150 in tubular member 125. Further, slit 135a is in communication with slit 135 in tubular member 125. The modification of balloon dilation catheter 100 illustrated in Figure 4 eliminates the need for having opening 130 disposed in tubular member 125 illustrated in Figure 1.

With reference to Figures 5-9, the delivery of balloon dilation catheter 100 will be described.

As is known in the art, catheterization is normally performed to alleviate a lesion in an artery. This is shown schematically in Figures 6-9 wherein a lesion in the form of a blockage 15 obstructs an artery 20. In certain cases, it is desirable to deploy a stent at the site of the lesion to maintain the patency of artery 20 at the site of blockage 15. As shown in Figure 5, catheterization is performed through an incision in the groin area of the patient.

Thus, with reference to Figures 6 and 7, a guide catheter 25 is initially delivered into artery 20 to a region proximal of blockage 15. The proximal end of guide catheter 25 remains outside the patient.

Balloon dilation catheter 100 (Figure 1) has mounted on balloon 115 thereof a stent 30. Further, guidewire 160 in second lumen 150 such that it emanates from opening 130 and from distal end 110 of balloon dilation catheter 100. Preferably, this is achieved in a conventional manner by feeding guidewire 160 into second lumen 150 at distal end 110 of balloon dilation catheter 100 until the proximal end of guidewire 160 emanates from opening 130.

At this point, balloon dilation catheter 100 is inserted into guide catheter 25 and guidewire 160 is navigated through artery 20 to a point distally of blockage 15 (Figure 7).

Alternatively, it is possible to advance guidewire 160 to a point distally of blockage 15, after which the distal end of second lumen 150 of balloon dilation catheter 100 is passed onto the proximal end of guidewire 160. If it becomes difficult to advance guidewire 160 across blockage 15 using this technique, it is possible to advance balloon dilation catheter over the proximal end of guidewire 160 until that end exits opening 130 and the system may be used in the "over-the-wire" approach described herein.

In Figure 8, there is illustrated removal of guidewire 160 while leaving balloon dilation catheter 100 in position at point proximal to blockage 15. This is an advantageous feature of the present balloon dilation catheter which is not possible with the balloon dilation catheter taught in Horzewski. Thus, guidewire 160 may simply be replaced with another guidewire by removing the original guidewire from proximal end 105 of balloon dilation catheter 100

and simply inserting a replacement guidewire (not shown) into the proximal end 105 of balloon dilation catheter 100 and through tubular member 125. Thereafter, the replacement guidewire may be navigated so that it emanates from distal end 110 of balloon dilation catheter 100. The replacement guidewire is navigated to a point distal of blockage 15.

5 Balloon dilation catheter 100 is then navigated over the replacement guidewire such that stent 30 is in proper position with respect to blockage 15 (Figure 8). Once the guidewire and balloon dilation catheter 100 are in the correct position, fluid is injected into first lumen 150 thereby expanding balloon 115 and stent 30 mounted thereon. Deployment of a stent in this manner is conventional and within the purview of a person skilled in the art.

10 In Figures 10 and 11, there is illustrated rapid exchange of balloon dilation catheter 100 while leaving guidewire 160 in place. In this case, for clarity, stent 30 is not shown on balloon 115. One of the features of the present balloon dilation catheter which distinguishes it from that in Horzewski is that guidewire 160 emanates from a proximal portion of balloon dilation catheter 100 which is always outside the body of the patient. This provides the
15 practitioner with the "over-the-wire" approach described above. Thus, either opening 130 is located outside the body at all times during use of catheter 100 illustrated in Figure 1 or it is necessarily emanating from the proximal end of balloon dilation catheter 100 if the modified embodiment in Figure 4 is utilized.

When it is desired to exchange balloon dilation catheter 100, the balloon dilation
20 catheter is withdrawn from artery 20 while leaving guidewire 160 in place. As balloon dilation catheter 100 is withdrawn from the body of the patient, it may be readily separated from guidewire 160 via slit 135 along virtually the entire length of tubular member 125 - this is one of the principal advantages of the present balloon dilation catheter which, to the knowledge of the present inventors, has not been achieved with a prior balloon dilation
25 catheter. Once distal end 110 of balloon dilation catheter 100 is withdrawn from the body, balloon 115 may be exchanged from guidewire 160 in a conventional manner.

A replacement balloon dilation catheter may then be fed over guidewire 100 and navigated into artery 20 in the area of blockage 15.

With reference to Figure 12, there is illustrated yet a further alternate embodiment to the present balloon dilation catheter. In this case, a slit 135b is provided in balloon 115b such that slit 135 is in communication with slit 135b on balloon 115b. This modification of balloon catheter 100 is particularly advantageous when the catheter is being used in an angioplasty application (i.e., without a stent mounted on balloon 115) as a pre-dilation balloon catheter allowing for enhanced rapid exchange features by facilitating withdrawal of guidewire 160 in a rapid exchange manner along virtually the entire length of tubular member 125 and balloon 115b via the combination of slits 135 and 135b. This feature is generally advantageous since it facilitates withdrawal of the balloon dilation catheter from the patient.

With reference to Figure 13, there is illustrate a preferred modification to tubular member 125 of balloon catheter 100. Specifically, a third lumen 180 is provided along substantially the entire length of tubular member 125. Disposed within third lumen 180 is a stiffening member 185 which serves to improve the "torqueability" of balloon dilation catheter. Unlike, the approach in Horzewski described above wherein a single lumen does double duty for receiving: (i) a stiffening member along most of the length of the catheter and (ii) the guidewire along a minor portion of its length, the approach shown in Figure 13 is a significant improvement over Horzewski since it maximizes both the distance over which rapid exchange may be effected and the distance over which stiffening may be conferred to the tubular member.

While this invention has been described with reference to illustrative embodiments, this description is not intended to be construed in a limiting sense. For example, while the illustrated embodiments depict use of the present balloon dilation catheter in delivery of a stent, those of skill in the art will immediately appreciate that the present balloon dilation catheter may be used in percutaneous transluminal coronary angioplasty techniques. Various modifications of the illustrative embodiments, as well as other embodiments of the invention, will be apparent to persons skilled in the art upon reference to this description. It is therefore contemplated that the appended claims will cover any such modifications or embodiments.

All publications, patents and patent applications referred to herein are incorporated by reference in their entirety to the same extent as if each individual publication, patent or

patent application was specifically and individually indicated to be incorporated by reference in its entirety.

What is claimed is:

1. A balloon dilation catheter comprising:
 - a tubular member having a proximal end and a distal end;
 - an inflatable balloon disposed at the distal end of the tubular member;
 - a first lumen disposed in the tubular member and in communication with an interior of the inflatable balloon;
 - a second lumen disposed in the tubular member for receiving a guidewire substantially along its entire length, the second lumen having a first opening at the proximal end of the tubular member and a second opening at the distal end of the tubular member; and
 - a first slit disposed longitudinally from the first opening along substantially the entire length of the tubular member to permit separation of the guidewire with respect to the second lumen.
2. The balloon dilation catheter defined in claim 1, wherein the first slit extends from the first opening to an area on the tubular member which is proximal to the inflatable balloon.
3. The balloon dilation catheter defined in claim 1, wherein the slit extends from the first opening to the second opening.
4. The balloon dilation catheter defined in claim 1, wherein the inflatable balloon comprises a second slit in substantial alignment with the first slit.
5. The balloon dilation catheter defined in claim 4, wherein at least a portion of the second slit is reinforced.
6. The balloon dilation catheter defined in claim 1, further comprising a third lumen for receiving a stiffening member.

7. The balloon dilation catheter defined in claim 6, further comprising the stiffening member disposed in the third lumen.
8. The balloon dilation catheter defined in claim 6, wherein the third lumen at least partially encompasses the second lumen.
9. The balloon dilation catheter defined in claim 7, wherein the stiffening member comprises a metal wire.
10. The balloon dilation catheter defined in claim 1, wherein the first lumen and the second lumen each comprise a passageway having a substantially circular cross-section disposed in a substantially solid tubular member.
11. The balloon dilation catheter defined in claim 1, further comprising at least one radioopaque marker disposed on the tubular member.
12. The balloon dilation catheter defined in claim 1, wherein the tubular member is constructed from plastic material having various density to provide a decreasing stiffness from the proximal end to the distal end.
13. A catheterization kit comprising:
 - a guide catheter;
 - a guide wire; and
 - a balloon dilation catheter comprising: a tubular member having a proximal end and a distal end; an inflatable balloon disposed at the distal end of the tubular member;
 - a first lumen disposed in the tubular member and in communication with an interior of the inflatable balloon; a second lumen disposed in the tubular member for receiving the guidewire substantially along its entire length, the second lumen having a first opening at the proximal end of the tubular member and a second opening at the distal end of the tubular

member; and a first slit disposed longitudinally from the first opening along substantially the entire length of the tubular member to permit separation of the guidewire with respect to the second lumen.

14. The catheterization kit defined in claim 13, wherein the first slit extends from the first opening to an area on the tubular member which is proximal to the inflatable balloon.

15. The catheterization kit defined in claim 13, wherein the slit extends from the first opening to the second opening.

16. The catheterization kit defined in claim 13, wherein the inflatable balloon comprises a second slit in substantial alignment with the first slit.

17. The catheterization kit defined in claim 16, wherein at least a portion of the second slit is reinforced.

18. The catheterization kit defined in claim 13, wherein the balloon dilation catheter further comprises a third lumen for receiving a stiffening member.

19. The catheterization kit defined in claim 18, further comprising the stiffening member disposed in the third lumen.

20. The catheterization kit defined in claim 18, wherein the third lumen at least partially encompasses the second lumen.

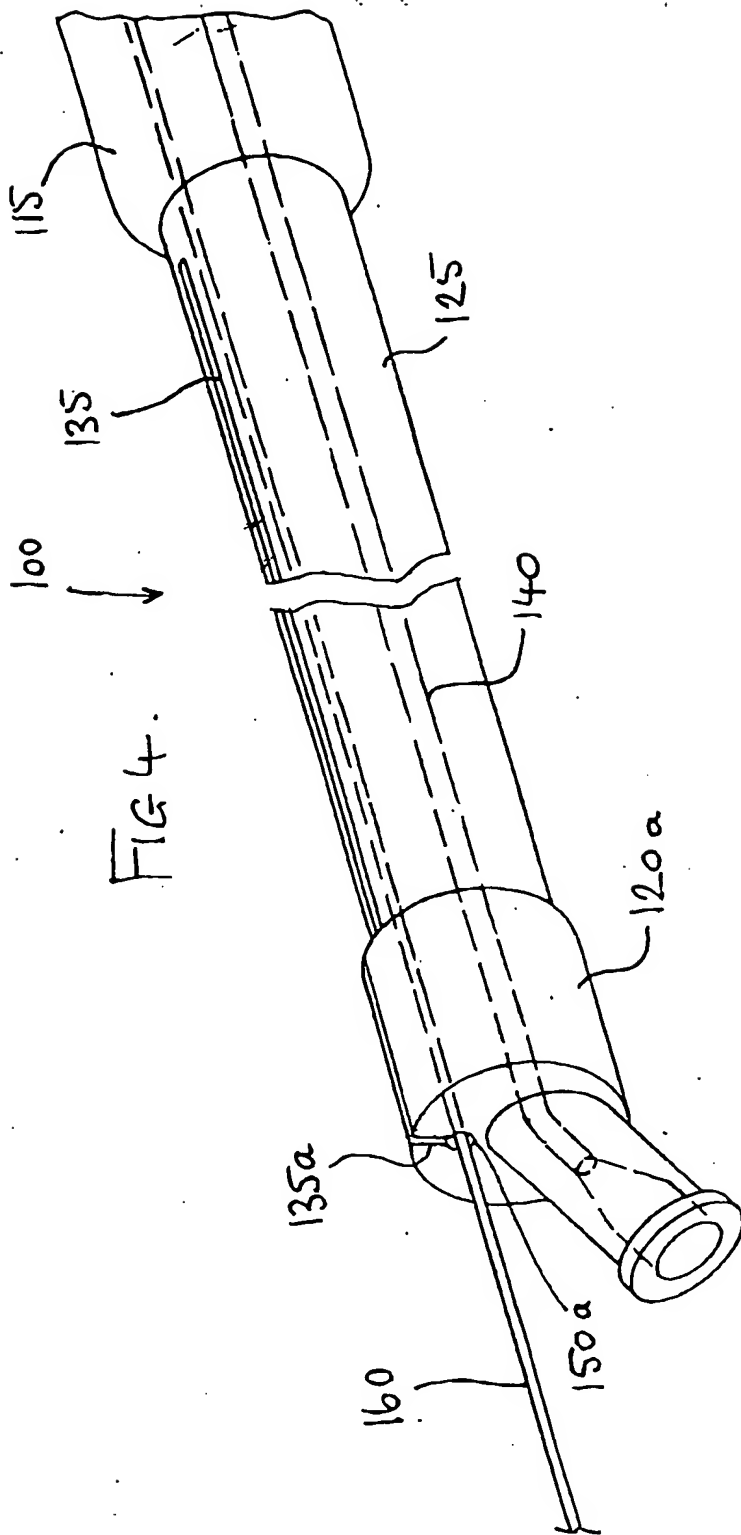
21. The catheterization kit defined in claim 18, wherein the stiffening member comprises a metal wire.

22. The catheterization kit defined in claim 13, wherein the first lumen and the second lumen each comprise a passageway having a substantially circular cross-section disposed in a substantially solid tubular member.
23. The catheterization kit defined in claim 13, wherein the balloon dilation catheter further comprises at least one radioopaque marker disposed on the tubular member.
24. The catheterization kit defined in claim 13, wherein the tubular member is constructed from plastic material having various density to provide a decreasing stiffness from the proximal end to the distal end.
25. A stent-mounted balloon catheter comprising:
a tubular member having a proximal end and a distal end;
an inflatable balloon disposed at the distal end of the tubular member;
a stent mounted on the inflatable balloon;
a first lumen disposed in the tubular member and in communication with an interior of the inflatable balloon;
a second lumen disposed in the tubular member for receiving a guidewire substantially along its entire length, the second lumen having a first opening at the proximal end of the tubular member and a second opening at the distal end of the tubular member; and
a first slit disposed longitudinally from the first opening along substantially the entire length of the tubular member to permit separation of the guidewire with respect to the second lumen.
26. The balloon catheter defined in claim 25, wherein the first slit extends from the first opening to an area on the tubular member which is proximal to the inflatable balloon.
27. The balloon catheter defined in claim 25, wherein the slit extends from the first opening to the second opening.

28. The balloon catheter defined in claim 25, wherein the inflatable balloon comprises a second slit in substantial alignment with the first slit.
29. The balloon catheter defined in claim 28, wherein at least a portion of the second slit is reinforced.
30. The balloon catheter defined in claim 25, further comprising a third lumen for receiving a stiffening member.
31. The balloon dilation catheter defined in claim 30, further comprising the stiffening member disposed in the third lumen.
32. The balloon catheter defined in claim 30, wherein the third lumen at least partially encompasses the second lumen.
33. The balloon catheter defined in claim 31, wherein the stiffening member comprises a metal wire.
34. The balloon catheter defined in claim 25, wherein the first lumen and the second lumen each comprise a passageway having a substantially circular cross-section disposed in a substantially solid tubular member.
35. The balloon catheter defined in claim 25, further comprising at least one radioopaque marker disposed on the tubular member.
36. The balloon catheter defined in claim 25, wherein the tubular member is constructed from plastic material having various density to provide a decreasing stiffness from the proximal end to the distal end.

ABSTRACT OF THE DISCLOSURE

A balloon dilation catheter comprising: a tubular member having a proximal end and a distal end and an inflatable balloon disposed at the distal end of the tubular member. The tubular member comprises a first lumen disposed in communication with an interior of the inflatable balloon and a second lumen for receiving a guidewire substantially along the entire length of the tubular member. The second lumen has a first opening at the proximal end of the tubular member and a second opening at the distal end of the tubular member. A first slit is disposed longitudinally from the first opening along substantially the entire length of the tubular member to permit separation of the guidewire with respect to the second lumen. The subject balloon dilation catheter provides improved rapid exchange advantages of either the catheter or the guidewire used in a catheterization technique.



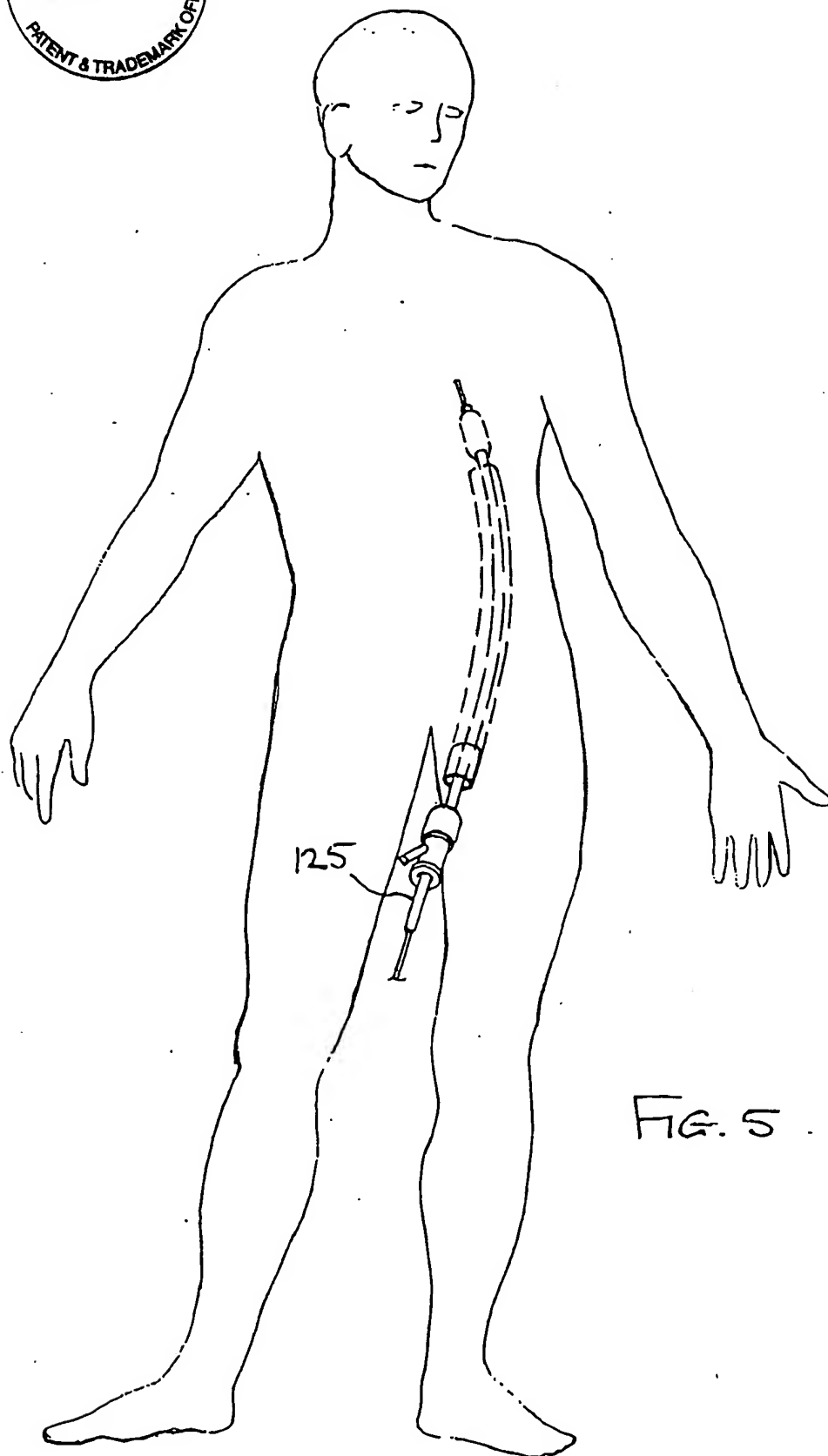
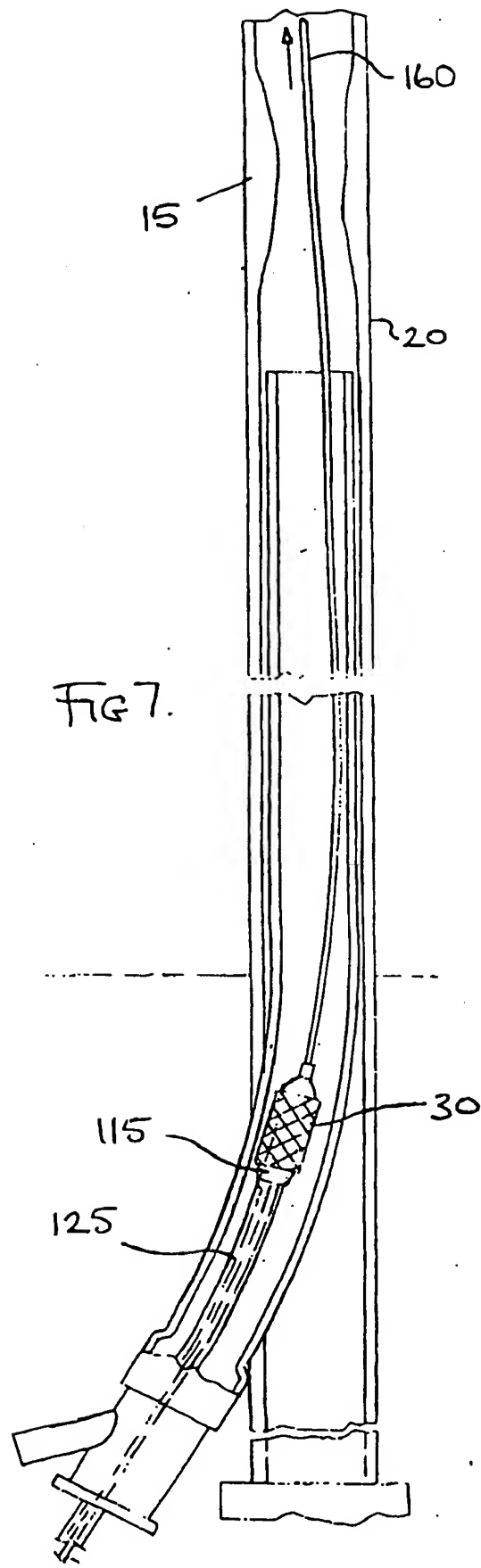
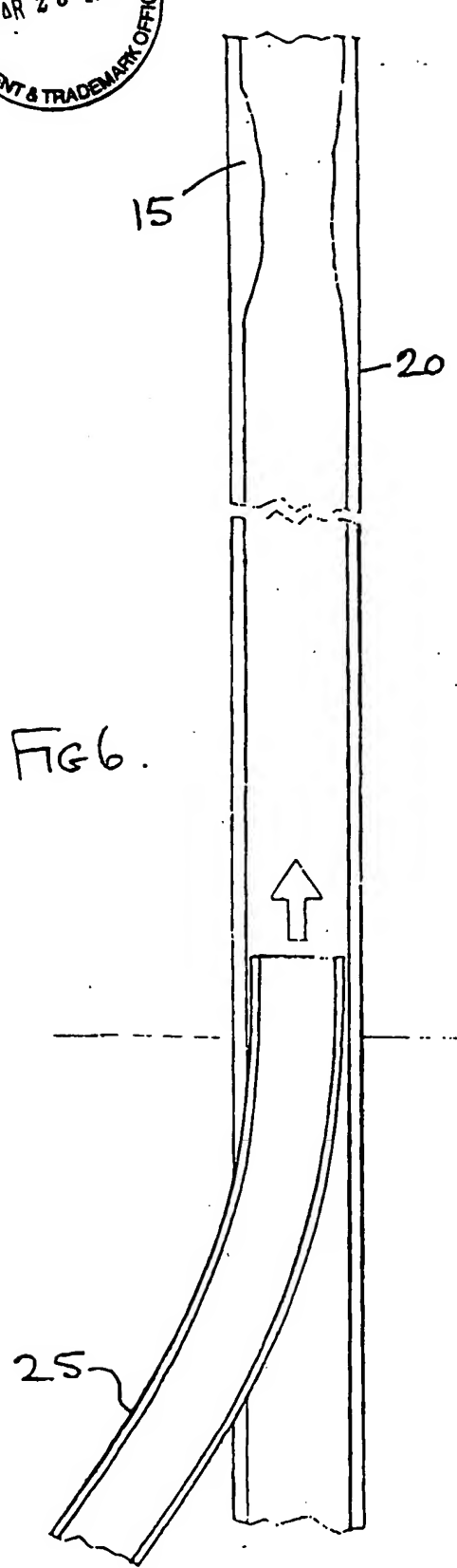


FIG. 5





C.

D.

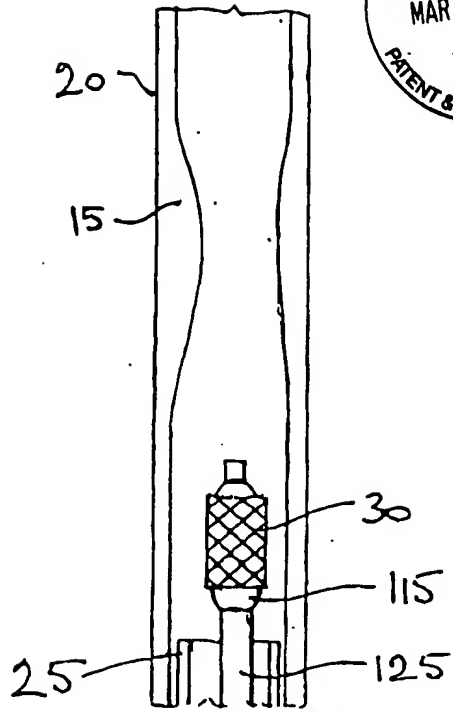


FIG 8.

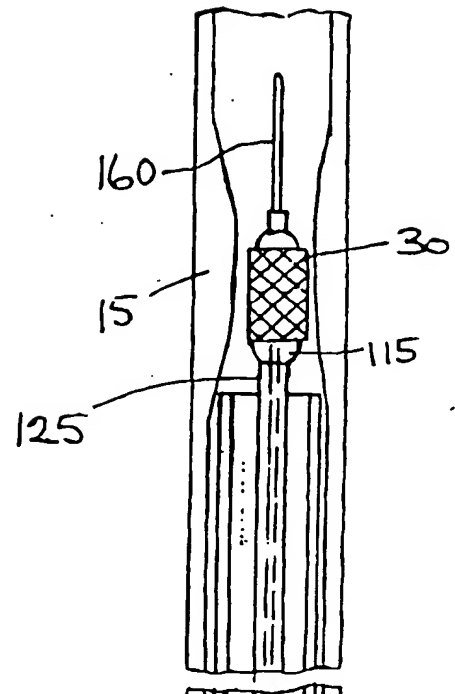


FIG 9.

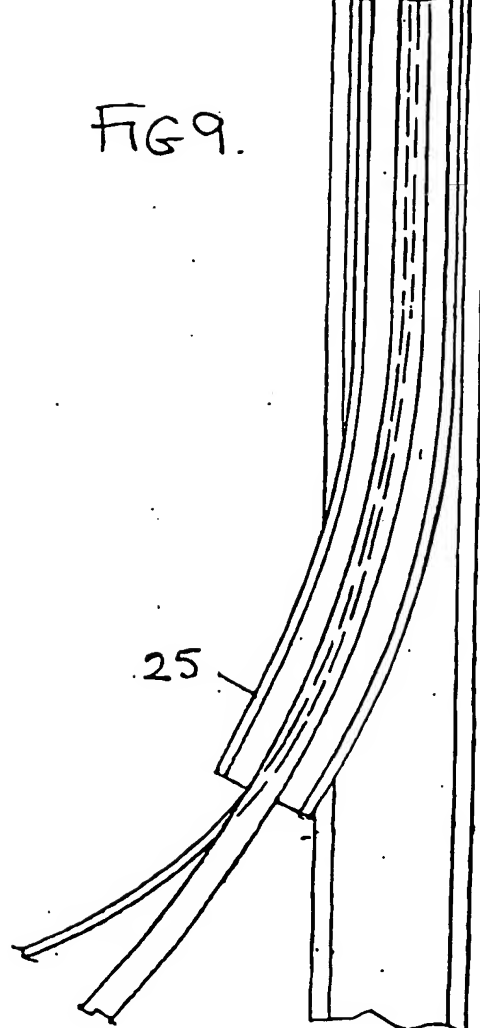
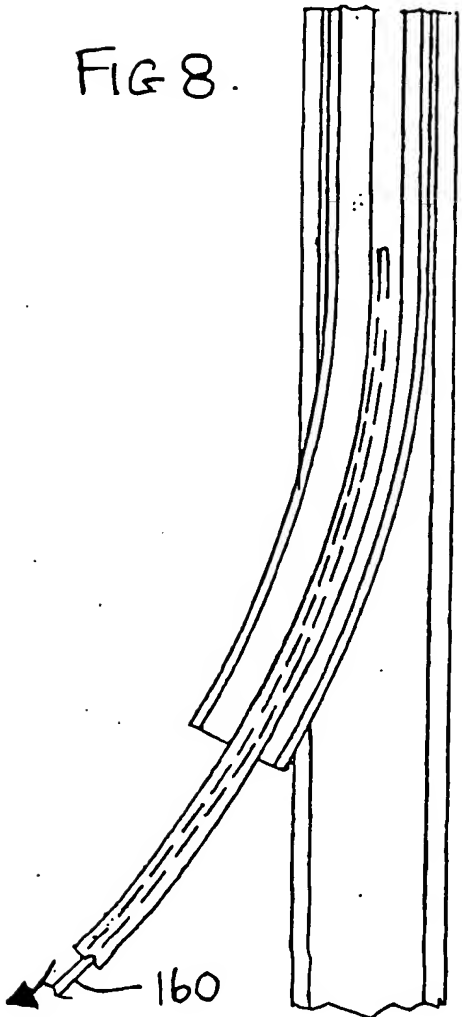




FIG 12.

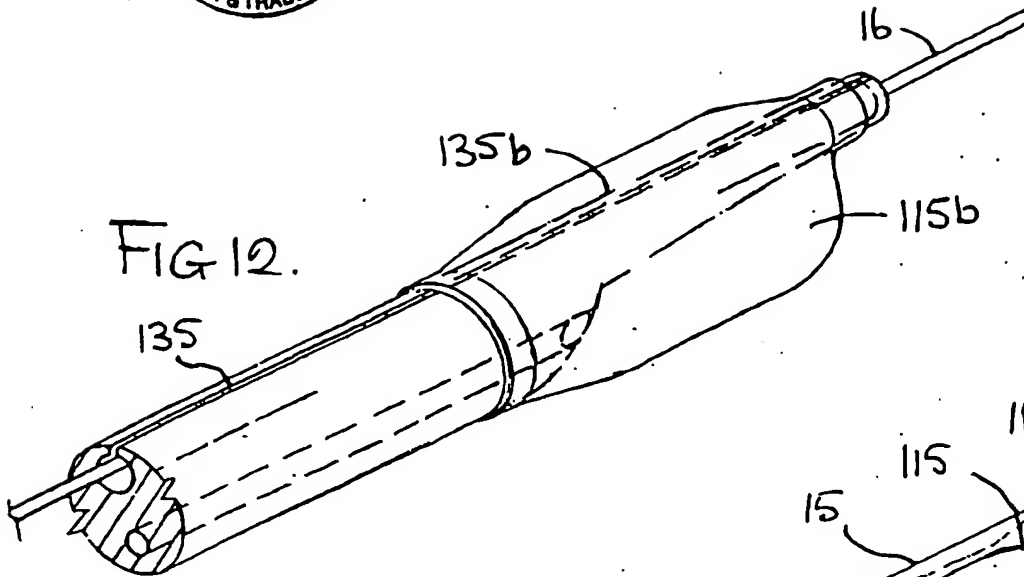


FIG 10.

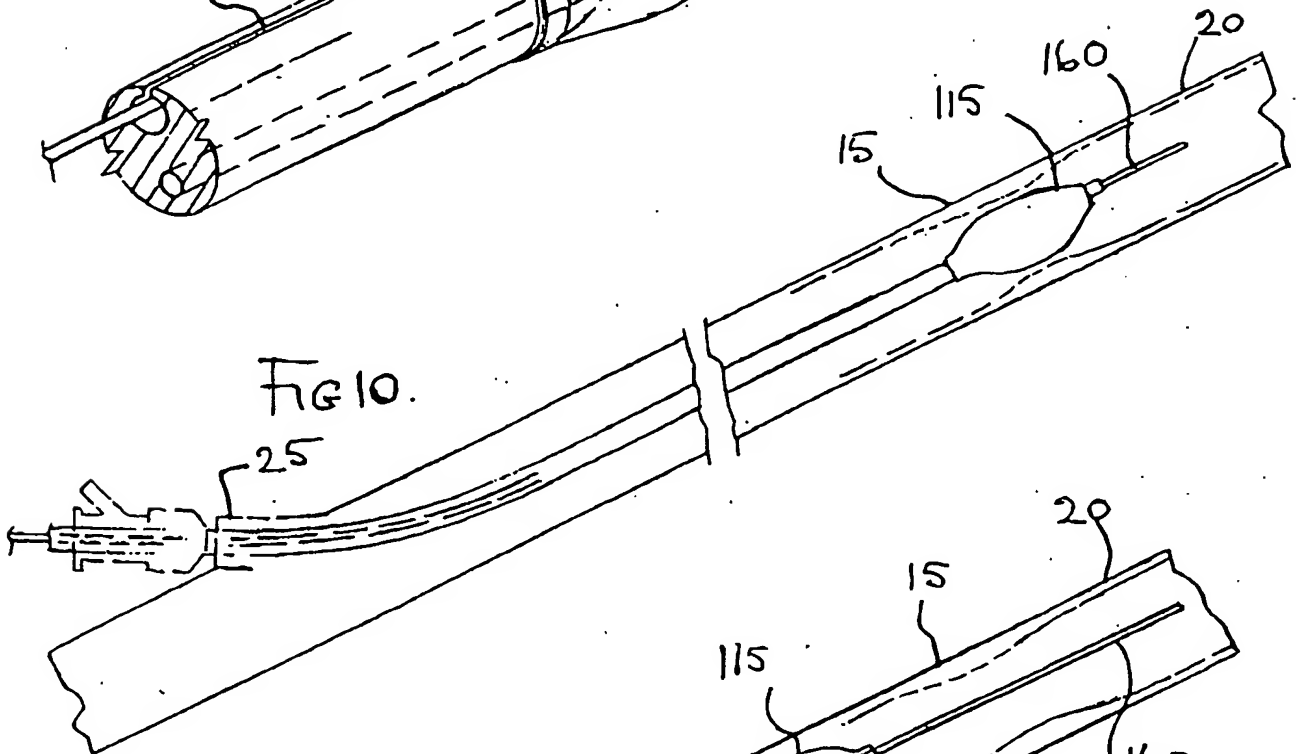


FIG 11.

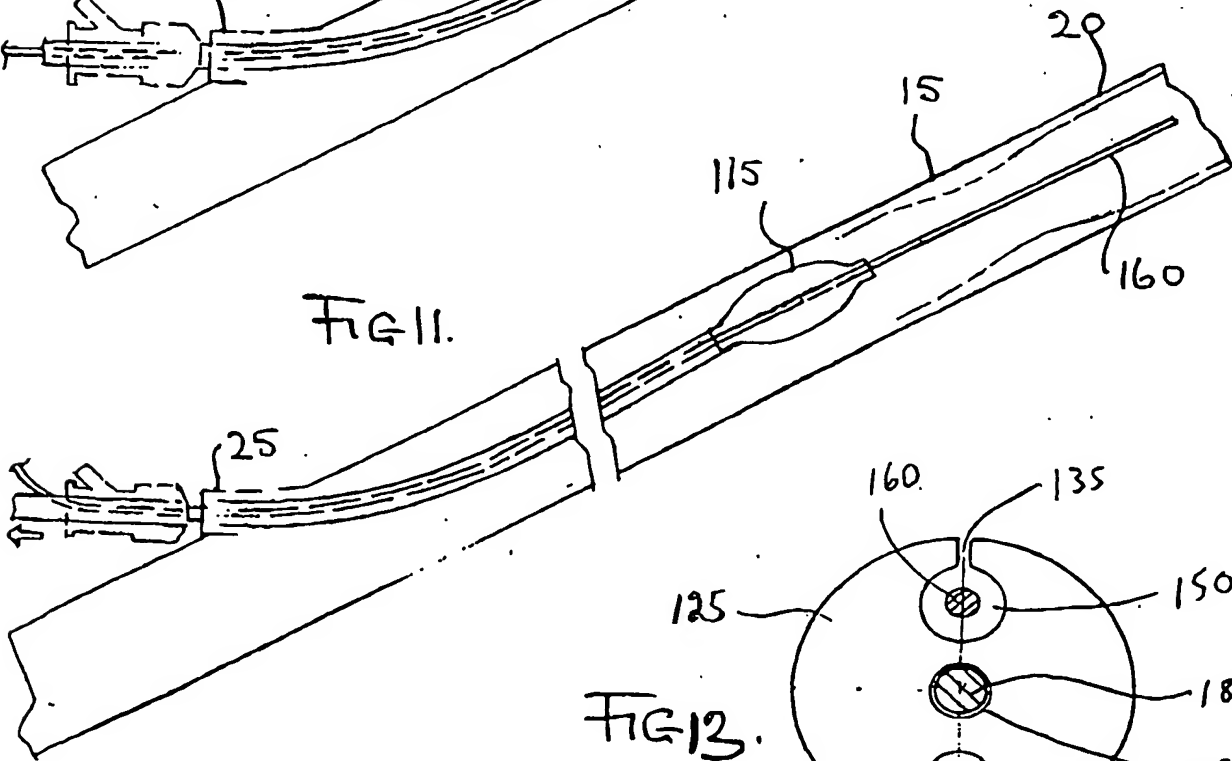
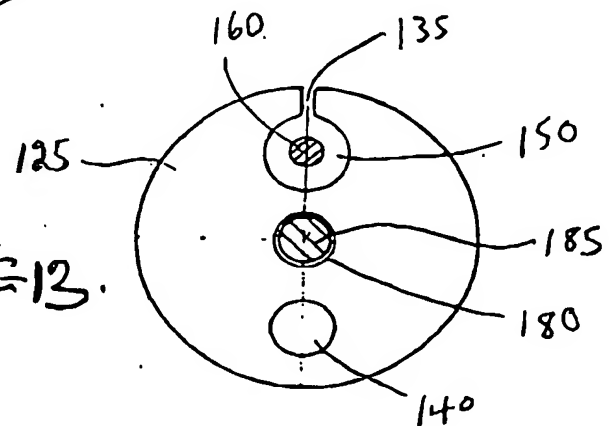


FIG 13.





**COMBINED DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION**

(Page 1)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my
name;

I believe I am an original, first and joint inventor of the subject matter which is
claimed and for which a patent is sought on the invention entitled STENT DELIVERY SYSTEM
AND METHOD OF USE, the specification of which ☒ is attached hereto ☐ was filed on _
_ as United States Application No. or PCT International Application No. _
and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the
above-identified specification, including the claims, as amended by any amendment referred to
above.

I acknowledge the duty to disclose information which is material to patentability
as defined in 37 CFR §1.56.

I hereby claim foreign priority benefits under 35 U.S.C. §119(a)-(d) or §365(b), of
any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international
application which designates at least one country other than the United States, listed below and have
also identified below any foreign application for patent or inventor's certificate, or PCT international
application having a filing date before that of the application on which priority is claimed:

<u>Country</u>	<u>Application No.</u>	<u>Filed (Day/Mo./Yr.)</u>	<u>(Yes/No)</u> <u>Priority Claimed</u>
----------------	------------------------	----------------------------	--

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States
provisional application(s) listed below:

<u>Application No.</u>	<u>Filed (Day/Mo./Yr.)</u>
------------------------	----------------------------

I hereby claim the benefit under 35 U.S.C. § 120 of any United States
application(s), or § 365(c) of any PCT international application designating the United States, listed
below and, insofar as the subject matter of each of the claims of this application is not disclosed in

**COMBINED DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION**

(Page 2)

the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.


	Status	
<u>Application No.</u>	<u>Filed (Day/Mo./Yr.)</u>	<u>(Patented, Pending, Abandoned)</u>

I hereby appoint the practitioners associated with the firm and Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith, and direct that all correspondence be addressed to the address associated with that Customer Number.

FITZPATRICK, CELLA, HARPER & SCINTO
Customer Number: 05514

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of Sole or First Inventor RICCI, Donald R.

Inventor's signature 

Date February 11, 2000 Citizen/Subject of Canada

Residence 4443 West 3rd Avenue, Vancouver, British Columbia,
Canada, V6R 1M9

Post Office Address same as residence

Full Name of Second Joint Inventor, if any _____

Second Inventor's signature _____

Date _____ Citizen/Subject of _____

Residence _____

Post Office Address _____

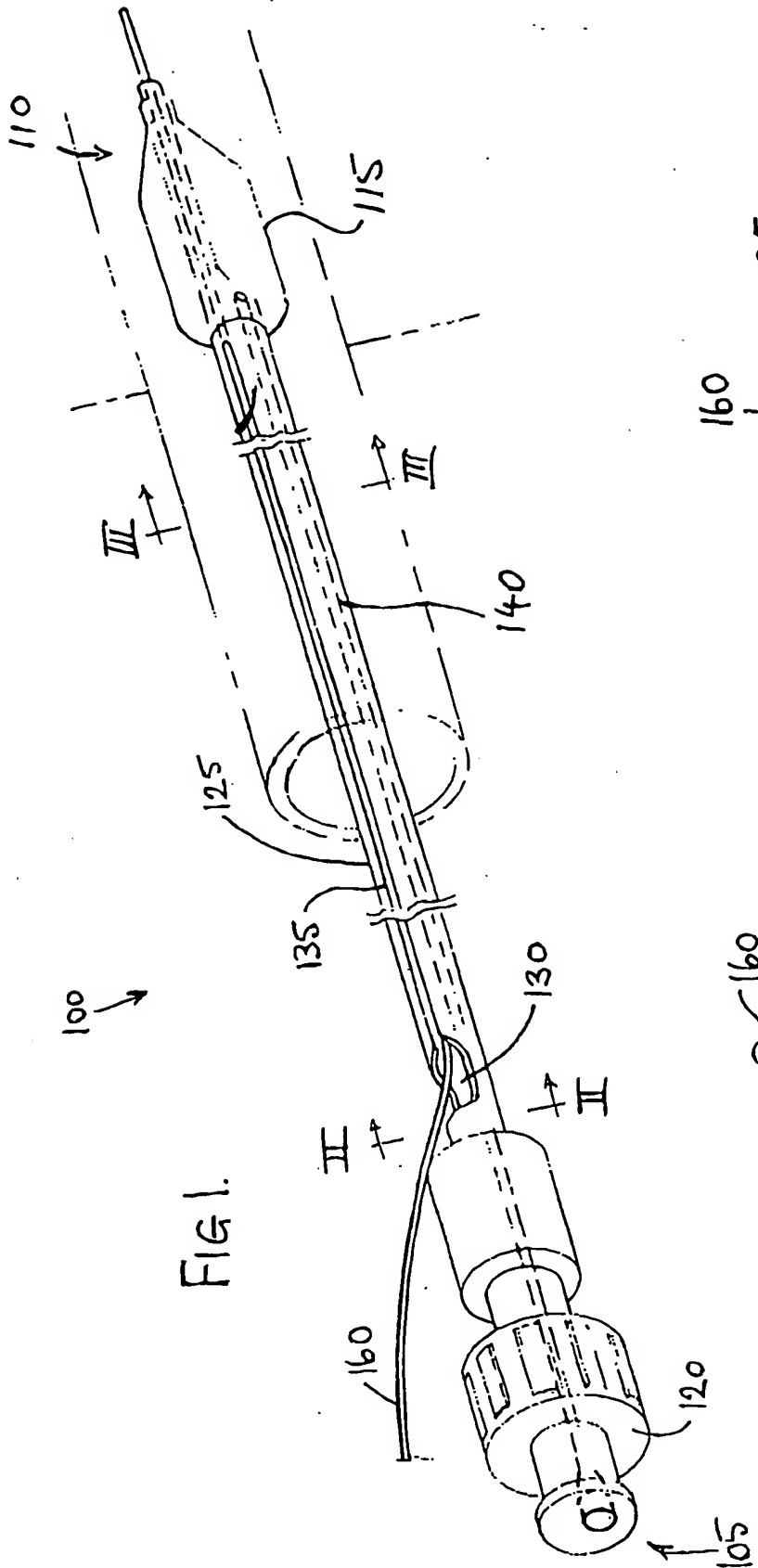


FIG. 1.

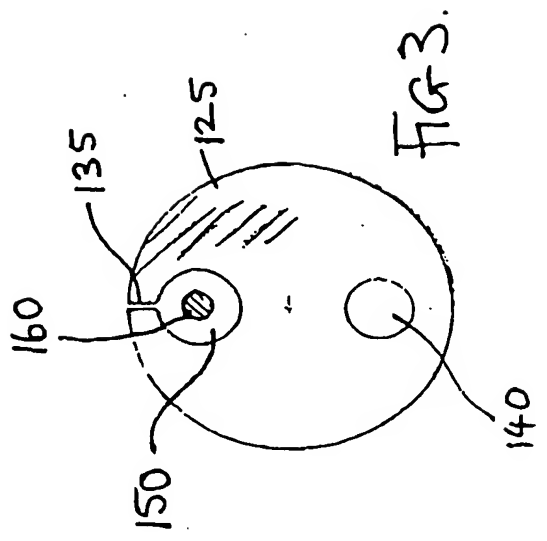


FIG. 3.

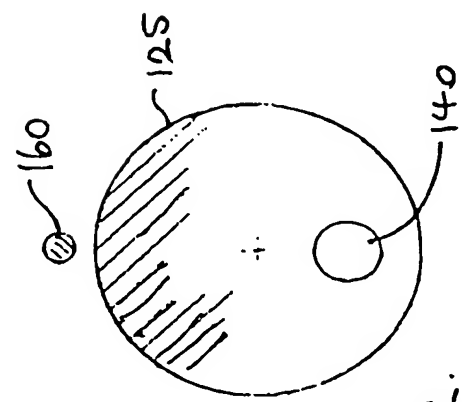


FIG. 2.





213202.00483

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
DONALD R. RICCI)	Examiner: L. Thanh
Application No.: NYA)	Group Art Unit: 3763
Filed: September 29, 2003)	
For: STENT DELIVERY SYSTEM)	September 29, 2003
AND METHOD OF USE)	

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the documents listed on the enclosed Form PTO-1449. Copies of the listed documents have been provided in parent Appln. No. 09/501,981.

CONCLUSION

It is respectfully requested that the below-listed information be considered by the Examiner and that a copy of the enclosed Form PTO-1449 be returned indicating that such information has been considered.

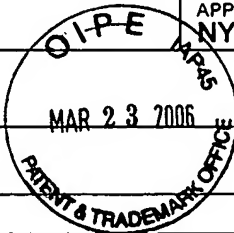
Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3507. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

Attorney for Applicant

Registration No. _____

PATENT ADMINISTRATOR
KATTEN MUCHIN ZAVIS ROSENMAN
525 West Monroe Street
Suite 1600
Chicago, Illinois 60661-3693
Facsimile: (312) 902-1061

FORM PTO 1449 (modified) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)				ATTY DOCKET NO. 213202.00483		APPLICATION NO. NYA	
				APPLICANT DONALD R. RICCI			
				FILING DATE September 29, 2003			
				GROUP 3763			
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		5,458,613	10/95	Gharibadeh, et al.			
		5,685,847	11/97	Barry			
		5,554,118	09/96	Jang			
		6,007,517	12/99	Anderson			
		4,748,982	06/88	Horzewski, et al.			
		5,569,296	10/96	Marin, et al.			
		5,334,187	08/94	Fischell, et al.			
		5,792,114	08/98	Fischell, et al.			
		5,205,822	04/93	Johnson, et al.			
		5,290,232	03/94	Johnson, et al.			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES/NO/ OR ABSTRACT
OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)							
EXAMINER				DATE CONSIDERED			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Atty. Dkt. No.: 213202.00483

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
	:	Examiner: L. Thahn
DONALD R. RICCI)	
	:	Group Art Unit: 3763
Application No.: NYA)	
	:	
Filed: September 29, 2003)	
	:	
For: STENT DELIVERY SYSTEM)	
AND METHOD OF USE	:	September 29, 2003
)	

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Sir:

Prior to examination on the merits, kindly amend the
above-identified application as follows:

Amendments to the specification begin on page 2 of this
paper.

Amendments to the claims are reflected in the listing
of claims which begins on page 5 of this paper.

AMENDMENTS TO THE SPECIFICATION:

Before the first line, kindly insert the following paragraph:

This application is a continuation of U.S. Patent Appln. No. 09/501,981, filed February 11, 2000, incorporated herein by reference.

Please replace the last full paragraph on page 7 with the following new paragraph:

Specifically, in Figure 4, Luer-type adaptor 120a is modified to contain a lumen 150a in communication with a slit 135a. As will be apparent to those of skill in the art, lumen 150a is in communication with second lumen 150 in tubular member 125. Further, slit 135a is in communication with slit 135 in tubular member 125. The modification of balloon dilation catheter 100 illustrated in Figure 4 eliminates the need for having opening 130 disposed in tubular member 125 illustrated in Figure 1. As is clear to the person of ordinary skill in the art, Figure 4 clearly shows that slit 135a is as narrow as slit 135; and Figure 3 clearly shows that slit 135 is narrower than the outside diameter of guidewire 160. Figure 4 also clearly shows that the slit 135a is straight throughout the length of the adapter.

As taught in Horzewski (incorporated herein by reference in the last paragraph of this specification), at Column 3, lines 31-36, and with reference to Figure 1 of Horzewski, radiopaque

marker means is provided in the form of radiopaque bands (27 and 28) which are secured to the tubular member within the balloon near the distal and proximal extremities of the balloon. Suitable material such as gold, tungsten or platinum may be utilized for the bands.

At Column 2, lines 30-68, Horzewski teaches that, in order to achieve the desirable stiffness for the shaft, the tubular member may be formed so that it has varying degrees of stiffness with decreasing stiffness towards the distal extremity of the same. The tubular member can be formed of a suitable material such as a polyolefin of various densities. The formation of the tubular member having different outside diameters and/or materials having different stiffnesses can be readily accomplished by extruding the two portions in separate extrusions using the desired ratio of high density and low density materials.

Further, Horzewski teaches at Column 4, lines 16-34 (and with reference to Figure 7 of Horzewski), that if it is desired to provide additional stiffness in the proximal extremity of the tubular member, a mandrel (34) can be inserted into the portion of the lumen (16) proximal of the plug (31) to serve as a stiffener. The mandrel can have suitable dimensions, as for example, a portion having a continuous diameter of approximately 0.020 inches for approximately 98 centimeters of its length from its proximal extremity, with a distal portion having a continuous taper of 10 centimeters tapering down to a final dimension of

approximately 0.012 inches. The mandrel can be utilized for properly positioning a plug in the first lumen and can be left in place to serve as the stiffener. The mandrel can be formed of a suitable material such as stainless steel. If the mandrel is to be used as a stiffener it is preferable to flatten approximately 1 centimeter of the distal top of the mandrel and locate this portion within the plug to secure the mandrel in place.

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claims 1-24 (cancelled)

25. (Currently Amended) A balloon catheter comprising:

a tubular member having a proximal end and a distal end;

an inflatable balloon disposed at the distal end of the tubular member;

a stent mounted on the inflatable balloon;

a first lumen disposed in the tubular member and in communication with an interior of the inflatable balloon;

a second lumen disposed in the tubular member for receiving a guidewire substantially along its entire length, the second lumen having a first opening at the proximal end of the tubular member and a second opening at the distal end of the tubular member;

a first slit disposed longitudinally from the first opening along the tubular member to permit separation of the guidewire with respect to the second lumen

an adapter disposed at the proximal end of said tubular member; and

an adapter slit disposed in said adapter to permit separation of the guidewire from the adapter, said adapter slit

being narrower than an outside diameter of the guidewire, said adapter slit being straight from a proximal end of the catheter to a distal end of the adapter.

Claim 26 (original) The balloon catheter defined in claim 25, wherein the first slit extends from the first opening to an area on the tubular member which is proximal to the inflatable balloon.

Claim 27 (original) The balloon catheter defined in claim 25, wherein the slit extends from the first opening to the second opening.

Claim 28 (original) The balloon catheter defined in claim 25, wherein the inflatable balloon comprises a second slit in substantial alignment with the first slit.

Claim 29 (cancelled)

Claim 30 (original) The balloon catheter defined in claim 25, further comprising a third lumen for receiving a stiffening member.

Claim 31 (original) The balloon dilation catheter defined in claim 30, further comprising the stiffening member disposed in the third lumen.

Claim 32 (cancelled)

Claim 33 (original) The balloon catheter defined in claim 31, wherein the stiffening member comprises a metal wire.

Claim 34 (original) The balloon catheter defined in claim 25, wherein the first lumen and the second lumen each comprise a passageway having a substantially circular cross-section disposed in a substantially solid tubular member.

Claim 35 (original) The balloon catheter defined in claim 25, further comprising at least one radioopaque marker disposed on the tubular member

Claim 36 (original) The balloon catheter defined in claim 25, wherein the tubular member is constructed from plastic material having various density to provide a decreasing stiffness from the proximal end to the distal end.

37. (New) The balloon catheter defined in claim 25, wherein said adapter slit consists of a straight slit throughout the length of said adapter.

38. (New) A balloon catheter comprising:
a tube having a proximal end and a distal end;
a balloon disposed at the distal end of the tube;
a stent mounted on the balloon;
a first lumen disposed in the tube and in communication with an interior of the balloon;

a second lumen disposed in the tube configured for receiving a guidewire along the length of the second lumen, the second lumen having a first opening at the proximal end of the tube and a second opening at the distal end of the tube;

a first slit disposed longitudinally from the first opening along the tube member to permit separation of the guidewire from the second lumen through the first slit;

an adapter connected to the proximal end of said tube;
and

an adapter slit disposed in said adapter to permit separation of the guidewire from the adapter through the adapter slit, said adapter comprising a straight slit throughout the entire length of said adapter from a proximal end of the catheter to a distal end of the adapter.

39. (New) The balloon catheter defined in claim 38, wherein said adapter slit is narrower than an outside diameter of the guidewire.

40. (New) The balloon catheter defined in claim 39, wherein said adapter slit is as narrower as said first slit.

41. (New) The balloon catheter defined in claim 39, wherein, wherein the balloon has a second slit in substantial alignment with the first slit.

42. (New) The balloon catheter defined in claim 39, wherein, wherein the tube is constructed from plastic material having various densities to provide a decreasing stiffness from the proximal end to the distal end.

43. (New) The balloon catheter defined in claim 39, wherein said first slit extends from the first opening along the length of the tube to a location proximal the balloon.

44. (New) . A stent-mounted balloon catheter comprising:

- a tube having a proximal end and a distal end;
- a balloon disposed at the distal end of the tube;
- a stent mounted on the balloon;

a first lumen disposed in the tube and in communication with an interior of the balloon;

a second lumen disposed in the tube configured for receiving a guidewire along the length of the second lumen, the second lumen having a first opening at the proximal end of the tube and a second opening at the distal end of the tube;

a first slit disposed longitudinally from the first opening along the tube member to permit separation of the guidewire from the second lumen through the first slit;

an adapter connected to the proximal end of said tube;

an adapter slit disposed in said adapter to permit separation of the guidewire from the adapter, said adapter slit being narrower than an outside diameter of the guidewire, said adapter slit comprising a straight slit; and

a third lumen disposed in said tube between the first and second lumens, a stiffening member being disposed in at least a portion of said third lumen.

45. (New) The balloon catheter defined in claim 39, wherein said adapter comprises:

a guidewire branch; and

an inflation branched angled with respect to said guidewire branch.

46. (New) The balloon catheter defined in claim 39, wherein said adapter has at least two sections with different diameters.

47. (New) A balloon catheter comprising:
a tubular member having a proximal end and a distal end;
an inflatable balloon disposed at the distal end of the tubular member;
a stent mounted on the inflatable balloon;
a first lumen disposed in the tubular member and in communication with an interior of the inflatable balloon;
a second lumen disposed in the tubular member for receiving a guidewire along at least a portion of its length, the second lumen having a first opening at the proximal end of the tubular member and a second opening at the distal end of the tubular member;
an adapter disposed at the proximal end of said tubular member; and
an adapter slit disposed in said adapter to permit separation of the guidewire from the adapter, said adapter slit being narrower than an outside diameter of the guidewire throughout the entire length of the adapter, said adapter slit comprising a straight slit from a proximal end of the catheter to a distal end of the adapter.

48. (New) The balloon catheter defined in claim 47, wherein said adapter slit is as narrower as said first slit.

49. (New) The balloon catheter defined in claim 47, wherein the inflatable balloon has a second slit in substantial alignment with the first slit.

50. (New) The balloon catheter defined in claim 47, wherein said first slit is narrower than an outside diameter of the guidewire.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3507. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

Attorney for Applicant
Registration No. 31,588

PATENT ADMINISTRATOR
KATTEN MUCHIN ZAVIS ROSENMAN
525 West Monroe Street
Suite 1600
Chicago, Illinois 60661-3693
Facsimile: (312) 902-1061



Atty. Dkt. No.: 213202.00196

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
DONALD R. RICCI)
Application No.: 09/501,981)
Filed: February 11, 2000)
For: STENT DELIVERY SYSTEM)
AND METHOD OF USE)
Examiner: L. Thahn
Group Art Unit: 3763
September 29, 2003

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION UNDER 37 C.F.R. 1.136(a)

Sir:

Applicant petitions the Commissioner of Patents to further extend the time for responding to the final Office Action dated August 28, 2002 (the time for responding to which has already been extended to February 28, 2003 by the filing of a Petition for Extension of Time and a Notice of Appeal on February 27, 2003) for five (5) months from April 27, 2003 to September 27, 2003.

Please charge Deposit Account No. 50-1710 \$985.00 to cover the fee for the extension under 37 C.F.R. § 1.17. Any deficiency in or overpayment of this fee should be charged or credited to Deposit Account No. 50-1710. A duplicate copy of this petition is enclosed.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3507. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

Attorney for Applicant
Registration No. 31,588

PATENT ADMINISTRATOR
KATTEN MUCHIN ZAVIS ROSENMAN
525 West Monroe Street
Suite 1600
Chicago, Illinois 60661-3693
Facsimile: (312) 902-1061



Prev. Dated.
CKE

Mail Stop *Patent appn.*
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Date 9/29/03
Atty. Docket No.: 213202
00483

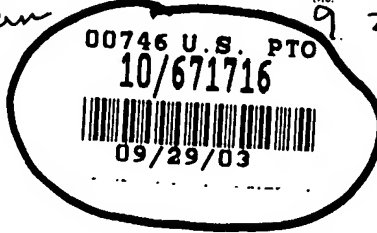
Sir:

Kindly acknowledge receipt of the accompanying:

- ☒ Specifications, claims and abstract 17 pages, with Transmittal Form.
- ☒ Oath or Declaration and Power of Attorney ☒ Executed ☐ Not Executed *copy*
- ☒ 6 Sheets of Formal ☒ Informal Drawings
- ☒ Check for \$ 455.00 (filing fee) *Dep. Acct.*
- ☒ Small Entity Declaration
- ☐ Assignment, PTO-1595 and Check for \$
- ☒ Transmittal Under 37 C.F.R. § 1.136 and Check for \$ 985 (Dep. Acct.)
- ☒ Other (specify) *Prelim. Amended FDSW/144; Ret Under*

by placing your receiving date stamp hereon and returning to deliverer.
Atty./Sec.: _____ Due Date 9/29/03

RPBldem



*37 C.F.R. 1.136(a)
for 5 mo.
EOT*



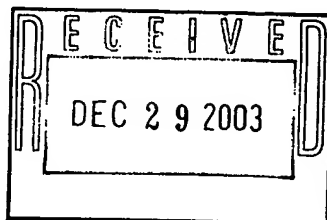
UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/671,716	09/29/2003	3739	453	213202.00483	6	24	4

CONFIRMATION NO. 9274

27160
PATENT ADMINISTRATOR
KATTEN MUCHIN ZAVIS ROSENMAN
525 WEST MONROE STREET
SUITE 1600
CHICAGO, IL 60661-3693



FILING RECEIPT



OC000000011549609

Date Mailed: 12/22/2003

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Donald R. Ricci, Vancouver, CANADA;

EXAMINED

CKL

Domestic Priority data as claimed by applicant

This application is a CON of 09/501,981 02/11/2000 ABN

Foreign Applications

If Required, Foreign Filing License Granted: 12/22/2003

Projected Publication Date: 04/01/2004

Non-Publication Request: No

Early Publication Request: No

** SMALL ENTITY **

Title

Stent delivery system and method of use

Preliminary Class

606

**LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15**

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

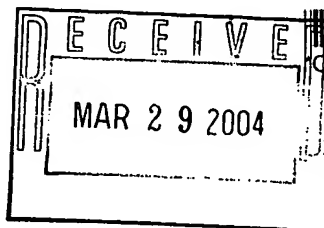


UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
10/671,716	09/29/2003	Donald R. Ricci	213202.00483

27160
PATENT ADMINISTRATOR
KATTEN MUCHIN ZAVIS ROSENMAN
525 WEST MONROE STREET
SUITE 1600
CHICAGO, IL 60661-3693



CONFIRMATION NO. 9274



Date Mailed: 03/11/2004

NOTICE OF NEW OR REVISED PROJECTED PUBLICATION DATE

The above-identified application has a new or revised projected publication date. The current projected publication date for this application is 05/20/2004. If this is a new projected publication date (there was no previous projected publication date), the application has been cleared by Licensing & Review or a secrecy order has been rescinded and the application is now in the publication queue.

If this is a revised projected publication date (one that is different from a previously communicated projected publication date), the publication date has been revised due to processing delays in the USPTO or the abandonment and subsequent revival of an application. The application is anticipated to be published on a date that is more than six weeks different from the originally-projected publication date.

More detailed publication information is available through the private side of Patent Application Information Retrieval (PAIR) System. The direct link to access PAIR is currently <http://pair.uspto.gov>. Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at (703) 305-3028.

Questions relating to this Notice should be directed to the Office of Patent Publication at (703) 305-8283.

PART 1 - ATTORNEY/APPLICANT COPY

DOCKETED



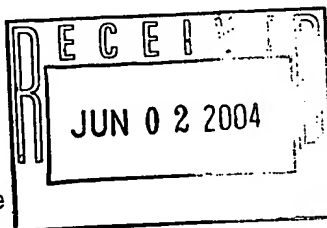
UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/671,716	09/29/2003	Donald R. Ricci	213202.00483

CONFIRMATION NO. 9274

27160
PATENT ADMINSTRATOR
KATTEN MUCHIN ZAVIS ROSENMAN
525 WEST MONROE STREET
SUITE 1600
CHICAGO, IL 60661-3693



DOCKETED

Title: Stent delivery system and method of use

Publication No. US-2004-0098085-A1
Publication Date: 05/20/2004

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publicly available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently <http://pair.uspto.gov/>. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at (703) 305-3028.

Customer Service Center
Initial Patent Examination Division (703) 308-1202

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

☒ **BLACK BORDERS**

☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**

☒ **FADED TEXT OR DRAWING**

☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**

☒ **SKEWED/SLANTED IMAGES**

☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**

☐ **GRAY SCALE DOCUMENTS**

☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**

☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**

☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.